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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,522	04/19/2006	Nancy Auestad	7278USol	3621
7590 Abbott Laboratories Patent and trademark Department Dept. 377 -AP6A-1 100 Abbott Park Road Abbott Park, IL 60064		EXAMINER EBRAHIM, NABILA G		
		ART UNIT 1618		PAPER NUMBER
		MAIL DATE 09/30/2009		DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,522

Applicant(s)

AUESTAD ET AL.

Examiner

NABILA G. EBRAHIM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1. Claim 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Oconnor et al. US publication 20020045660 (Oconnor).**

Oconnor teaches improved nutritional composition containing specified amounts of DHA and AA as well as their precursor essential fatty acids alpha-linolenic and linoleum acids. The methods involve feeding LCP supplemented, nutrient-enriched formulas for an extended feeding regimen, typically until at least 3 months corrected age (CA), preferably to 6 or even 12 months CA. The neurological developments such as visual development, and motor development were enhanced without findings of

anthropometric growth faltering or inhibition (abstract). Note that the lean body mass is mainly muscles and the motor development depends on muscles' mass.

O'Connor teaches also that infant formula is intended for full-term infants [0088], and recommends using enriched formula comprising DHA and AA for pre-term infants (abstract). O'Connor's formula contains the same amounts recited in the instant claims such as about 2-65 mg/kg body wt. of DHA and preferred 3-20 mg/kg body wt. and an amount of AA of 5-65 mg/kg body wt. preferred 5-40 mg/kg body wt. the formula is intended for infants of less than one year corrected age (See table "C" and claims 16 and 17). O'Connor discloses the values of caloric densities in different units; however, it is expected to be the same since the reference discloses the same compounds in the same amounts. Also instant claims 8 and 9 recite the amount of grams per each 100kcal of the formula which is also inherent since the reference discloses same amounts and percentages of kcal's. The protein, fat and carbohydrate components provide, respectively, from about 8 to 10, 46 to 50 and 41 to 44% of the calories; and the caloric density ranges narrowly from about 660 to about 700 kcal/L [0088]. Regarding claims 12-14 that recite amount of DHA and AA as a percentage of the total fatty acids in the formula, O'Connor describes similar percentages [0088].

O'Connor discloses a formula comprising the same fatty acids for improving the neurological and motor development, though the reference does not disclose literally the effect of a formula comprising DHA and AA on the growth of lean mass or the reduction of fat mass, it is noted that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by

identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding instant claim 16, it is noted that evaluating infant growth is done periodically as a routine and was done and disclosed by O'Connor (see tables).

The new amendments to the claims including limiting the infants to preterm infants, reciting all the results of administering the ARA and DHA in a formula would not differentiate the instant claims over the prior art. It is noted that Koletzko discloses the use of the same formula to the premature infants in the same amounts recited in the instant claims and the results obtained from administering the formula is inherent and will be obtained even if the purpose of the method was different. In addition, the recitation of the source of the LCPUFA was also disclosed by Koletzko in the reference.

2. Claims 1, 5 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Koletzko, Fatty Acids And Early Human Growth, American Journal of Clinical Nutrition, Vol. 73, No. 4, 671-672, April 2001 (Koletzko).

Koletzko teaches that pre- and post-natal essential fatty acid supply and metabolism are related to infant growth. The provision of infant formulas with a balanced supply of dietary AA and DHA in reasonable amounts and with adequate antioxidant protection, which is recommended by many experts worldwide, did not lead to poor growth or other adverse effects in several randomized clinical trials (see page 672, left

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column). The LCPUFA are of fish oil origin (page 672) and the formula is given to infant who are born prematurely (page 671).

Koletzko teaches the use of AA and DHA in reasonable amounts to full-term infants because it is correlated to weight growth. Koletzko teaches the use of DHA and ARA in full-term infant feeding without adverse effects, the instant claims recited a method of using same compounds, the method comprises one step of feeding an infant a nutritional formula comprising DHA and ARA to increase lean body mass and reduce fat body mass in infants. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established.

The new amendments to the claims including limiting the infants to preterm infants, reciting all the results of administering the ARA and DHA in a formula did not differentiate the instant claims over the prior art. It is noted that O'Connor discloses the use of the same formula to the premature infants in the same amounts recited in the instant claims and the results obtained from administering the formula is inherent and will be obtained even if the purpose of the method was different. In addition, the recitation of the source of the LCPUFA was also disclosed by O'Connor in the reference.

Therefore, claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

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Conclusion: Claims 1, 5, and 11 are anticipated by Koletzko.

3. Claims 1, 5, and 10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Innis SM. et al., Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in pre-term infants fed formula, J Pediatr. 2002 May;140(5):547-54 (Innis).

Innis teaches that Feeding DHA+ARA from single-cell triglycerides enhance weight gain in formula-fed premature infants with no evidence of adverse effects. Claim 1 recites that "DHA and ARA reduces fat body mass", consequently, it is inherent that these compounds will have the same effect on infants who are fed formulas comprising DHA and ARA. Innis teaches the use of DHA and ARA in infant feeding to enhance growth, the instant claims recite a method of using same compounds, the method comprises a customary step of feeding an infant a nutritional formula comprising DHA and ARA to increase lean body mass and reduce fat body mass in infants. The reference teaches that the ARA is from fungus origin (page 549) and the DHA is from fish oil origin. (page 548)

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

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The new amendments to the claims including limiting the infants to preterm infants, reciting all the results of administering the ARA and DHA in a formula did not differentiate the instant claims over the prior art. It is noted that Innis discloses the use of the same formula to the premature infants in the same amounts recited in the instant claims and the results obtained from administering the formula is inherent and will be obtained even if the purpose of the method was different. In addition, the recitation of the source of the LCPUFA was also disclosed by Innis in the reference.

Conclusion: claims 1, 5, and 10 are anticipated by Innis.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. US publication 20020045660 in view of Thierry Raclot et al. "Site-specific Regulation of Gene Expression by - Polyunsaturated Fatty Acids in Rat White Adipose Tissue" Journal of Lipid Research, Vo. 38, 1997 Pages 1963-1972 (Racolt), the reference was provided by Applicant in the IDS dated 8/7/2006.

O'Connor is relied upon for the reasons set forth hereinabove.

O'Connor did not teach literally that long chain polyunsaturated fatty acids reduce fat body mass.

Raclot studied the effect of dietary n-3 PUFAs given as eicosapentaenoic acid (EPA group), decosahexaenoic acid (DHA group). The reference concluded that n-3 PUFAs limit abdominal fat depot hypertrophy.

Thus, it would have been obvious to a person having ordinary skill in the art the include the long chain the fatty acids ARA and DHA in a premature infant formula to achieve the increase of the muscular tissue while limiting the increase in fat cell size as disclosed by the combination of O'Connor and Racolt. The artisan would expect success in making a formula for infants specifically premature infants who are in need for healthy compensatory growth.

Response to Arguments

Applicant's arguments filed 6/30/2009 and 9/10/2009 have been fully considered but they are not persuasive. Applicant argues that:

Claim Rejections under 35 USC § 102:

Applicant argues that O'Connor, Innis and Koletzko fail to disclose or suggest feeding a nutritional formula comprising a source of DHA and ARA to an infant for the purpose of increasing lean body mass and reducing fat body mass.

This was not found persuasive because administering the same formula to the same population (premature infants) should produce the same results. Even if the references did not disclose literally these results, the reference clearly teaches that the formula enhances healthy growth. In addition, the results of increasing lean body mass and decreasing fat body mass cannot be avoided by any means since it is the result of the only step required for this instant method which is administering the formula comprising ARA and DHA to premature infants.

Further, Koletzko also discloses that it was reported that there was an inverse relation of total *trans* fatty acids to concentrations of various essential fatty acids in plasma lipids

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of both mothers and infants. Thus, since it is reported that the combination of ADA and DHA reduces plasma content of fat and consequently the fat that reaches the cells. In the mean time it correlates to weight growth, then it is expected that this growth is achieved in protein content of the cells (mainly muscular tissue).

Applicant also argues that finding of inherency cannot be based on mere assumptions by the office. Rather, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

This was not found persuasive because, it was known that n-3 PUFA reduce the adipose tissue (this is evidenced by Racolt, the reference being in record in the obviousness rejection). In addition, it is inherent that administering Aspirin as an anti-inflammatory would result in blood thinning, this is not avoidable since it is of the same dose and given to the same population in need.

Claim Rejections under 35 USC § 103:

The arguments render moot in view of the new grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art
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